Long-term Follow-up of Cytologically Indeterminate Nodules with Afirma GEC "Benign" Result

Sipos, Jennifer A.;[1] Sosa, Julie Ann;[2] Marqusee, Ellen;[3] Angell, Trevor;[3] Singer, Joseph[4]

1. Endocrinology, Ohio State University 2. Surgery, Duke University 3. Endocrinology, Brigham & Women's Hospital 4. Healthcore Inc

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

INTRODUCTION

Recent ATA and AACE guidelines have explicitly sought long-term outcome data regarding cytologically indeterminate nodules with Afirma GEC 'benign' results.

METHODS

A PubMed literature search for relevant original publications through May 22, 2016 was performed.

RESULTS

Six published clinical utility studies reported a median follow-up time of 7 months or longer, including 3 studies with ≥ 13 months follow-up (median 13, 19, and 26 months) **(Figure 1)**. The three studies include 411 GEC 'benign' results and the longest reported follow-up time was 44 months. Among these studies with median follow-up > 1 year (including 2 multicenter and 1 single center), 85% of GEC 'benign' patients avoided surgery on average. One study included histopathology results and reported 1 cancer among GEC 'benign' nodules (1.1%). Compared with cytopathology-benign nodules, there was no statistical difference in the proportion of nodules demonstrating growth (p=0.80) or cancer detection (p=0.16) **(Figure 2)**. Another multi-center study reported no statistical difference in the rate of follow-up ultrasound evaluation (p=0.70) or thyroid surgery (p=0.59) among GEC 'benign' vs cytopathology benign nodules **(Table 1)**.

CONCLUSIONS

Among cytologically benign nodules, guidelines indicate that nodules requiring follow-up should typically be re-evaluated within 12-24 months. GEC 'benign' nodules appear to behave like cytologically benign nodules and are managed similarly during long-term follow-up. More than 400 patients with GEC 'benign' results are described in the literature, with durations of follow-up sufficient to sustain their clinical observation until re-evaluation according to recent guideline recommendations. Most GEC benign nodules remain unoperated, and a low prevalence of cancer is reported among them.

FIGURE 1.

Literature Review Results

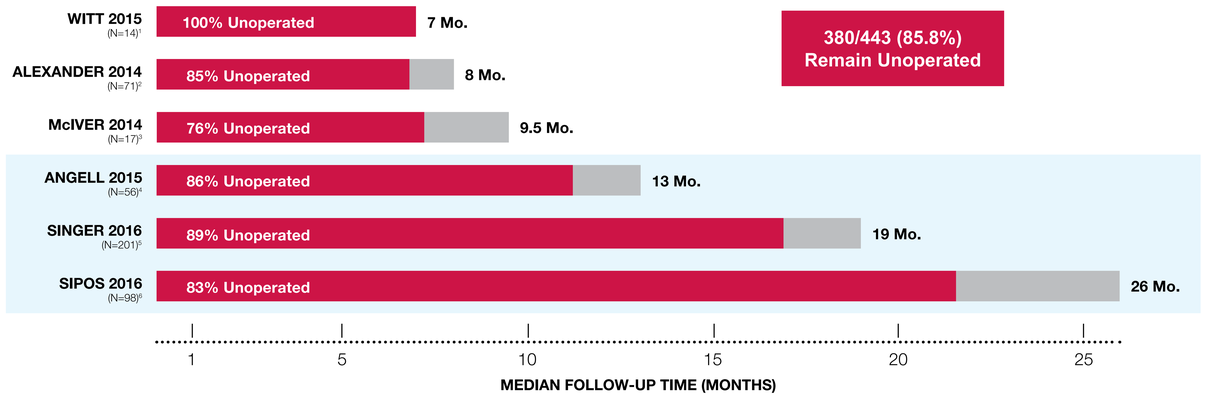
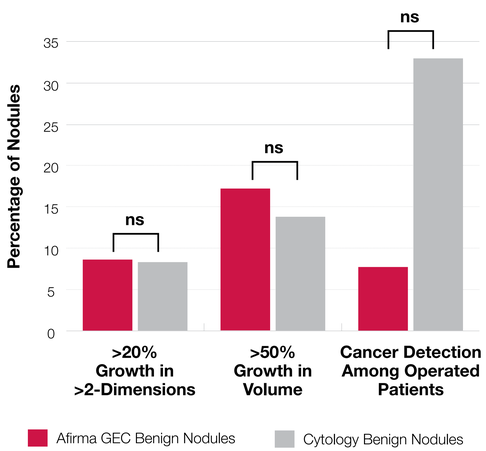


FIGURE 2.

Angell et al. Nodule Outcomes[4]



Nodule Outcomes for GEC Benign Nodules Compared to Cytologically Benign Nodules

Bar graphs representing the percentage of nodules meeting prespecified endpoints for 58 cytologically indeterminate and Afirma GEC Benign nodules (red bars) compared to 1224 cytologically benign nodules (gray bars).

ns = not significant

TABLE 1.

Singer et al. Nodule Outcomes[5]

	Afirma GEC Benign n = 201		Cytopathology Benign n = 603		P-Value
Age in Years at Index Date (n, SD)	50.5	12.4	50.5	12.1	0.968
% Female (n, %)	167	83.1%	501	83.1%	1.000
Nodule Size in cm (Mean, SD)	2.3	1.0	2.3	1.0	0.382
Any Ultrasound Exam (n, %)	**121**	**60.2%**	**372**	**61.7%**	**0.706**
Thyroid Surgery (n, %)	**23**	**11.4%**	**61**	**10.1%**	**0.594**

REFERENCES

1. Witt RL. *Laryngoscope*. 2015
2. Alexander EK, et al. *JCEM* 2014
3. McIver B, et al. *JCEM*. 2014
4. Angell TE et al. *JCEM*. 2015
5. Singer J, et al. *CMRO*. 2016
6. Sipos JA, et al. *Endocr Pract*. 2016